

**REMARKS****Anticipation Rejections**

With regard to the Examiner's rejection of claims 1-3 and claim 5, the Examiner argues that the claim is met by the teachings of the Wayne '791. The Wayne device teaches a technique for obliterating the left atrial appendage by essentially evert it, i.e. pulling it inside out. The implanted device left behind to achieve this result in one embodiment is shown in Fig. 27 b and c. This is the embodiment referred to by the Examiner in the action. Claim 1 and its dependent claims all require that the device be enlarged within the atrial appendage and the barrier extending across the ostium of the atrial appendage. In the embodiment taught by Fig. 27 b and c the ostium is obliterated and the device clamps down on the everted atrial appendage. For this reason the claim, which calls for enlarging a device within the atrial appendage, does not and cannot read on this embodiment of Wayne. For this reason the Applicant respectfully requests that the rejection under §102 be reconsidered and withdrawn.

With respect to the rejections of claims 85-90 and 180 the Examiner argues that the claim language is met by Wayne '791. In Wayne the basic teaching is that the left atrial appendage must be obliterated by reducing its volume. Various devices can be used to retain the LAA in a collapsed condition and these include the device shown in Fig. 29 of Wayne and described in column 12 of Wayne. In the embodiments of Wayne the left atrial appendage is collapsed and an implanted structure is used to retain it or pull it into a collapsed condition. This is different than the Applicant's invention set forth in claim 85, among others, that requires that the implanted device be deployed within the atrial appendage or adjacent an opening of the atrial appendage and provide circumferential sealing contact. Although not expressed explicitly in the claim this methodology both requires and assumes that the left atrial appendage be preserved. For this reason claim 85 calling for "enlarging" an implantable structure is not taught by the device of Wayne. Applicant requests reconsideration of this anticipation rejection in light of these comments.

Regarding claims 120-125, 128-131 and 179 the Examiner regards these claims as anticipated by Wayne '791. Claim 120 and related claims were previously amended to require the insertion of the implanted device within the atrial appendage in its collapsed configuration followed by subsequent enlargement of the implanted device.

As understood by Applicant the Wayne system is essentially the opposite in the sense that the left atrial appendage that is collapsed and the device 95 is deployed to retain the contracted defibrillation. There is no enlargement within the LAA, rather only contraction within the LAA. For this reason the Applicant respectfully requests the Examiner to reconsider the anticipation rejection based upon the teaching of Wayne

With respect to claims 134 and 136-138 the Examiner argues that Wayne '791 anticipates these claims directing attention to device 95 as described in column 12. The ambiguity inherent in the language of column 12 is clarified by reference to Fig. 31 a and b where the purse string strategy of reducing the volume and thereby obliterating the LAA is shown sequentially in panels 31 a and b. It is important to note that the pouch is not in fact the left atrial appendage but rather an eversion of the left atrial appendage and for this reason Applicant's claim as previously amended does not read on the Wayne disclosure. Applicant respectfully requests reconsideration of the anticipation rejection.

With respect to claims 141-142 the Applicant regards Wayne as an anticipatory reference directing attention to columns 4 and 5 of the Wayne reference. Claim 140 very clearly requires an in tact interior and ostium of the natural left atrial appendage to be present and participate in the percutaneous transvascular delivery of the implanted device. The Wayne reference does not meet these limitations since the catheter system is used to snag the LAA, pull it inside out and retain it in that position using one of a variety of mechanisms. For this reason the claim is not anticipated by the Wayne reference, and reconsideration of the rejection is respectfully solicited.

With regard to claims 145 and 151 the Examiner argues that these claims are anticipated by Wayne directing attention to the Fig. 29 embodiment of Wayne. Claim 145 and related dependent claims specifically call for device enlargement once deployed and positioned at the opening or ostium of the atrial appendage. The enlarged or deployed position also conforms to and contacts and intact inner wall tissue surface. The Fig. 29 device is never deployed in an in tact atrial appendage in the Wayne reference and for this reason cannot meet the limitation of the claim. Applicant respectfully requests reconsideration of this rejection.

With regard to claims 161-163 and 170-178 the Examiner argues that the self-expanding frame 95 meets the limitations of these claims. All of these claims require that the medical device be deployed within a naturally occurring left atrial appendage

in its normal position and confirmation. Although this is not explicit within the claims, Applicant will happily amend the claims to describe a naturally occurring LAA if that will improve the allowability of the claims and if the anticipation rejection is fundamentally an issue of claim scope based upon 112 issues.

### **Obviousness rejections**

The Examiner has rejected all of the claims under various combinations of the teaching of Wayne '791 and Kavetladze et al. The basic argument is that the Kavetladze reference shows expandable device with membranes to promote tissue growth and that this teaching when combined with various attributes of the Wayne teaching render the claims obvious to one of ordinary skill in the art.

In Applicant's view an obvious combination of these references would result in the adoption of the geometric properties of Kavetladze applied to the LAA obliteration and containment device called for by Wayne.

All of Applicant's claims require an intact naturally occurring left atrial appendage that is left in its natural position and which is covered by the implanted device. Neither reference provides this basic teaching and this leads one of ordinary skill in the art at a loss rather than in possession of the Applicant's invention. For example, regarding claims 4, 39, 40, et. seq. the Examiner argues that one of ordinary skill would adopt the disk shape from the Kavetladze and use that to prevent movement of thrombus from the appendage. The problem with the argument is that in Wayne the appendage has been obliterated. There is no appendage to be concerned with and the use of a mesh disk, although certainly extractable from the Kavetladze, has no meaning in this context. Wayne doesn't have a place to put a mesh disk.

Another example is related to the rejection of claims 50, 55 et. seq. Applicant will readily concede that porous mesh materials can be used to support tissue growth and that this is well known but the core teaching of LAA occlusion is not present in the combination of references or the argument.

Applicant invites a telephone conversation with the Examiner regarding the teaching of Wayne. There appears to be a fundamental disagreement as to the core teaching of Wayne, which may be clarified by a phone conversation.

Applicant respectfully requests the reconsideration of the rejections of the claims in light of these comments.

**CONCLUSION**

All of the claims remaining in this application should now be seen to be in condition for allowance. The prompt issuance of a notice to that effect is solicited.

Respectfully submitted,  
ATRTECH, INC.  
By its attorneys:

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Robert C. Beck  
Registration No. 28,184  
Beck & Tysver, P.L.L.C.  
2900 Thomas Ave., #100  
Minneapolis, MN 55416  
Telephone: (612) 915-9635  
Fax: (612) 915-9637